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TITLE: "Using Motivational Enhancement Among OIF / OEF Veterans Returning to the Community"

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14. ABSTRACT <p>The main objective of the study is to test a motivational enhancement (ME) intervention to address barriers to engaging in mental health treatment for recently returned veterans of Operation Iraqi Freedom and Operation Enduring Freedom. The long term goal of the study is to increase veteran's participation in mental health treatment by using a Stages of Change model to reduce perceived stigma and barriers to treatment. The central hypothesis put forth is that veterans who receive motivational enhancement will demonstrate greater readiness to change and higher treatment program attendance than veterans who receive treatment as usual. During this year the pilot study for the project was completed. The purpose of the pilot study group was to inform us of any changes and/or enhance user ability of the project manuals. However, due to the lapse in coverage the data collected from the pilot group members could not be used. The veterans in the pilot study were notified of the lapse and were re-consented. During the year the team has continued to brainstorm resources and methods to recruit OIF/OEF veterans for the study. It is a logistical matter that continues to be challenging. More efforts are being made to reach agencies that may encounter OIF/OEF veterans that qualify for the study. Hiring of the veterans to help with recruitment was somewhat helpful in that we received additional inquiries about the project, however, only a small number met the criteria for eligibility. We have found that two factors seem to be the predominant barriers to our recruitment processes: 1) Veterans must live in Wayne County; 2) Veterans must not be currently in counseling to participate in the project. To combat this, one idea proposed is to allow veterans who live outside of Wayne County to participate in the study. A second idea the team discussed is to open up recruitment to veterans that may be in treatment or have attended treatment briefly in the past. Currently, the study emphasis is on veterans that have not received any mental health treatment. This change can be supported by the literature in that many combat veterans do not enter treatment and if they do go to treatment they do not stay in treatment long. According to Dr. Murphy, most of the groups he has conducted were with veterans already in therapy. Those groups helped with veterans' treatment follow through. These changes are currently under review by the Wayne State University (WSU) IRB.</p>								
15. SUBJECT TERMS <u>WSU</u> : Wayne State University <u>Pilot Study</u> : Group of veterans recruited test the study's treatment manual and treatment processes for improvements and to enhance the veteran user ability of the treatment manual and related tools.								
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INTRODUCTION:

The main objective of the study is to test a motivational enhancement (ME) intervention to address barriers to engaging in mental health treatment for recently returned veterans of Operation Iraqi Freedom and Operation Enduring Freedom. The long term goal of the study is to increase veteran's participation in mental health treatment by using a Stages of Change model to reduce perceived stigma and barriers to treatment. The central hypothesis put forth is that veterans who receive motivational enhancement will demonstrate greater readiness to change and higher treatment program attendance than veterans who receive treatment as usual. The study consists of three parts:

Phase 1

The finalization and adaptation of the treatment plan and the training of treatment staff and peer support specialist.

Phase 2

The implementation of the ME group study intervention.

Phase 3

Collect data as to the best methods of recruiting veterans for the study and to evaluate their satisfaction with the intervention program.

Keywords:

Pilot Study: Group of veterans recruited test the study's treatment manual and treatment processes for improvements and to enhance the veteran user ability of the treatment manual and related tools.

WSU: Wayne State University

FMU: Francis Marion University

UP: Unexpected Problem

IRB: Internal Review Board

DoD: Department of Defense

Overall Project Summary:

An earmark was granted to the then Detroit-Wayne County Community Mental Health Agency. The project was for a 2 year period with a budget of \$524, 000. Then PI Elaine R. Thomas was informed by DoD that the project was not a service grant but a research project. As a result Wayne State University School of Social Work was contracted to write a proposal for the use of the funding. After many meetings, telephone conferences and resubmissions a proposal was agreed upon between Wayne County and the Department of Defense (DoD). The kickoff for this project was during the month of September 2011. It was entitled: Using Motivational Enhancement among OIF/OEF Veterans Returning to the Community.

Due to the amount of time it took for the project to be given approval by the various Universities and Agencies between the first and second years of the project, as well as, a few major organizational administrative changes, we requested and received a 'no cost extension' to continue our work on the project for the fiscal year 10/1/13-9/30/14. At the beginning of the year Detroit-Wayne County Community Mental Health Agency, Detroit, Michigan, became the Detroit-Wayne Mental Health Authority, Detroit, Michigan. During the year there were several logistical matters that the team has needed to address. First, continuation for the protocol was approved following Full Board review by the Wayne State University Institutional Review Board (B3) for the period of 02/20/2014 through 02/19/2015. However, the IRB application was submitted without sufficient time for approval before the expiration date of February 4, 2014. As a result, the project was out of compliance from February 4, 2014, through February 20, 2014. The Co- PI, Shirley Thomas, completed an Unexpected Problem (UP) Report Form dated February 19, 2014. The unexpected problem event reviewer examined the UP report and forwarded it to the full IRB for consideration. The IRB conducted an audit of the project and a full board review was conducted. On May 15, 2014 the B3 IRB met and discussed the audit results, which included that the PI agreed not to use the data collected on 6 participants and the PI's corrective action plan. The B3 IRB also discussed the auditor's recommendations that the correction action plan be made consistent with when the continuation will be filed, and to state what reminders the PI has in place to ensure timely submission of the continuation. The auditor also recommended that the study be re-audited in 6-months to ensure adherence in using the correct IRB-approved data collection tools and that the annual continuation process had been started.

The B3 IRB voted to accept the auditor's recommendations. The team is actively following the recommendations from the team and is scheduled for another audit October 15, 2014.

During the year the pilot study for the project was completed. The purpose of the pilot group was to inform any changes and/or enhance user ability of the project manuals. Due to the lapse in coverage any data collected from the pilot group members which began 2/6/14 could not be used. Six veterans in the pilot study were notified of the lapse and were re-consented. It should be noted that only two of the six veterans completed all six sessions of the group.

During the year the team has continued to brainstorm resources and methods to recruit OIF/OEF veterans for the study. It is a logistical matter that continues to be challenging. More efforts are being made to reach agencies that may encounter OIF/OEF veterans that qualify for the study. This includes attending stand downs; contacts with VFW members; internet use; as well as presenting to campus groups at universities and colleges. This year, we advertised the project on our campus web-site and streamed for a month on the CBS sports web-site. In addition, this year 2 veterans were hired to help with recruiting. The hiring of the veterans was somewhat helpful in that we received 13 inquiries about the project. However, only six met the criteria for eligibility. During this year we met again with the Veteran's Recruiting counselors on WSU campus. They recommended that we re-design our recruiting flyer and to re-think the county restriction on eligibility.

We have found there to be two major factors that have adverse impact on our recruitment process. One is that veterans must live in Wayne County and second is that veterans cannot be currently in counseling. To combat this, one idea is to allow veterans who live outside of Wayne County to participate in the study. A second idea the team discussed is to open up recruitment to veterans that may be in treatment or have attended treatment briefly in the past. Currently, the study emphasis is on veterans that have not received any mental health treatment. This change can be supported by the literature in that many combat veterans do not enter treatment and if they do go to treatment they do not stay in treatment long. According to Dr. Murphy, most of the groups he has conducted were with veterans already in therapy. The groups helped with veterans' treatment follow through. These changes are under review by the WSU IRB.

Within the last quarter of this year, our project milestones chart was revised and submitted with our request for a second 'No Cost Extension.' The request was approved 24-Sep-2014.

Also within the last quarter USMAMRC Contracting Officer, Dr. Kilpatrick and Project Officer, Ruchi Malik were assigned to monitor our project in early August 2014. Prior to the end of August, Ms Ramadonal replaced Ms. Muchi as our USMAMRMC Project Officer.

The project team continues to meet to monitor progress and address any unanticipated circumstances; this year there were 10 meetings and numerous emails and phone calls concerning this project.

Key Research Accomplishments:

Relative to our progress related to the adaption of an evidence-based intervention on motivational enhancement.

- A. Developed manual and training for motivational enhancement. We have completed this task. (It should be noted that after the completion of the pilot study additional minor changes were made to the manual making it final and it will be submitted to the WSU IRB and USAMRMC Office of Research Protection as an addendum for approval.)
- B. Expert review on content was obtained and considered.
- C. Pilot test of the protocol was conducted.
- D. Treatment staff and the Veteran Peer Support Specialist were trained.

Reportable Outcomes:

The updated project manuals will be submitted and approved by the WSU IRB within the month. It is anticipated that the change in our project eligibility requirements will also be approved by the WSU IRB. As noted, the project did receive a No Cost Extension allowing minimal disruption administering the project by Wayne Mental Health Authority, WSU, and FMU. The study team will continue to meet monthly and more

frequent when indicated, to monitor progress and attend recruiting events. Dr. Murphy of FMU will continue to oversee and supervise the training of the clinical staff to ensure fidelity to the model.

Dr. Shirley Thomas, Co-PI and Ellen Maher, RA will continue to find sites to recruit veterans for the study. This year we hope to enroll a minimum of 50 veterans in the study; collect pretest data; assign to conditions; and conduct weekly sessions of the ME protocol.

The updated Milestone chart is attached. In our revised project milestones it is our hope to complete the project by the end of the fiscal year 2015. This includes the completion of the data collection, analysis and write up of the results in the mandated timeframe.

Conclusion:

What follows are the proposed changes to complete the project within the performance period granted. Change our eligibility criteria to allow OIF/OEF veterans to participate in the study if they are actively in treatment and to reduce the number of veterans to participate in the study from 100 to 50.

Summary of timeline would be as follows:

September 2014

1. Apply for IRB approval for final version of manual.
2. Apply for NCE from the DoD
3. Submit changed protocol to Wayne State University IRB

October 2014

1. Approval from Wayne County IRB for final version of manual.
2. Approval from Wayne County IRB for changes to the protocol.
3. Submit changed protocol to Francis Marion IRB.
4. Undergo audit for IRB B3.

November 2014

1. Receive NCE decision from USAMRMC.
2. Continue recruiting study participants.

December 2014

1. Continue recruiting study participants.
2. Begin group intervention cycles.
3. Submit continuation for project to WSUIRB & USAMRMC, Office of Research Protections.

January 2015

1. Complete 1 cycle of group intervention.
2. Continue recruiting study participants.

February 2015

1. Begin cycle 2 of the group intervention.
2. Complete cycle 1 of the group intervention.

March 2015

1. Complete cycle 2 of the intervention.
2. Begin cycle 3 of the intervention.
3. Enter data from cycle 1.

April 2015

1. Complete cycle 3 of the intervention.
2. Enter data from cycle 2.

May 2015

1. Enter data from cycle 3.

June 2015

1. Begin Follow-up for cycle 1.
2. Enter data from cycle 1.

July 2015

1. Begin Follow-up for cycle 2
2. Enter data from cycle 3

August 2015

1. Begin Follow-up for cycle 3
2. Enter data for cycle 3

September 2015

1. Conduct Analysis

October 2015

1. Write up results and findings

Appendice

Attached is our milestone chart that details the revised project timeline.

Critical Events	Aug '14	Sep '14	Oct '14	Nov '14	Dec '14	Jan '15	Feb '15	March '15	April '15	May '15	June '15	Jul '15	Aug '15	Sep '15	Oct '15
1. Adapt ME Protocol															
a. Update ME intervention manual															
b. Submit revisions to Wayne State IRB															
c. Submit revisions to manual to TATRIC															
d. Submit changes to Francis Marion IRB															
e. IRB accept changes to ME manual															
f. Submit changes to study protocol to full board IRB															
g. IRB accepts changes to study protocol															
2. Participant Recruitment															
a. Secure agreements with community-based sites to recruit															
b. Conduct presentations to returning veterans															
c. Visit sites to recruit															
d. Mail letters and advertise in veteran newsletters															
e. Recruit 50 veterans for study															
3. Implement 3 cycles of study protocol.															
a. Screen 240 interested participants for eligibility															

b. Conduct interviews with participants to obtain consent, administer pretests, provide overview of project			C1	C2	C3						
c. Assign participants to conditions			C1	C2	C3						
d. Notify participants and SCS on next steps for experimental and control participants				C1	C2	C3					
e. Conduct orientation with veterans selected for ME intervention				C1		C2					
f. Conduct weekly group for veterans (6 weeks) using ME				C1	C1/C2	C2/C3	C3				
g. Participants have contact with Peer Support Specialist				C1		C2					
h. Conduct posttest assessment at end of ME protocol				C1		C2	C3				
4. Monitor TX & Participants											
a. Develop fidelity and tracking methods and instruments											
b. Peer Support Specialist maintain communication with veterans for follow-back											
c. Collect follow up data at 3 months									C1	C2	C3
5. Data Analysis											
a. Enter and clean pretest data				C1	C2	C3					
b. enter and clean posttest data					C1	C2	C3				
c. Conduct analysis											
d. Write up results and finding											